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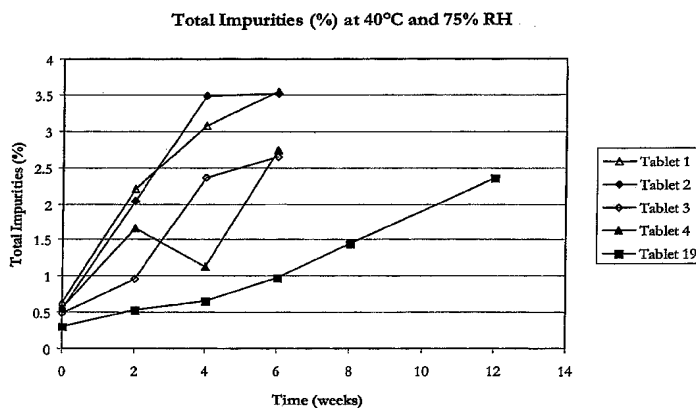
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(54) Title: STABLE PHARMACEUTICAL COMPOSITION COMPRISING AN ACE INHIBITOR



(57) Abstract: The present invention relates to a stable pharmaceutical composition comprising an ACE inhibitor or a pharmaceu-
tically acceptable salt or derivative thereof. In particular, the invention relates to a pharmaceutical composition, which comprises
an ACE inhibitor, or a pharmaceutically acceptable salt or a derivative thereof, and a C₁₆-C₂₈ glyceride. ACE inhibitors useful in
the present invention are susceptible to heat and/or mechanical stress-induced degradation. Preferred ACE inhibitors are ramipril,
trandolapril, quinapril and pharmaceutically acceptable salts and derivatives thereof. The composition of the present invention may
be for use as a medicament for the treatment or prevention of a cardiovascular disease, a coronary heart disease, a cerebrovascular
disease, a peripheral vascular disease, arrhythmia, hypertension, cardiac failure, cardiovascular death, myocardial infarction, stroke
or angina. The present invention further relates to a method of preparing the pharmaceutical composition of the present invention.
The present invention also relates to a method of providing a stable pharmaceutical composition comprising an ACE inhibitor, or a
pharmaceutically acceptable salt or derivative thereof, by incorporating a C₁₆-C₂₈ glyceride into the composition. The present inven-
tion further relates to a use of C₁₆-C₂₈ glyceride to provide a stable pharmaceutical composition comprising an ACE inhibitor or a
pharmaceutically acceptable salt or derivative thereof.



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PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference ASE/45032PCT	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/GB2005/050016	International filing date (day/month/year) 15/02/2005	(Earliest) Priority Date (day/month/year) 27/02/2004
Applicant NICHE GENERICS LIMITED		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

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It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐

The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. ☐

With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2.

☐

Certain claims were found unsearchable (See Box II).

3.

☐

Unity of invention is lacking (see Box III).

4. With regard to the **title**,

☐

the text is approved as submitted by the applicant.

☒

the text has been established by this Authority to read as follows:

STABLE PHARMACEUTICAL COMPOSITION COMPRISING AN ACE INHIBITOR

5. With regard to the **abstract**,

☒

the text is approved as submitted by the applicant.

☐

the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 2

☒

as suggested by the applicant.

☐

as selected by this Authority, because the applicant failed to suggest a figure.

☐

as selected by this Authority, because this figure better characterizes the invention.

b. ☐

none of the figures is to be published with the abstract.